### **REMARKS**

The above amendments and these remarks are responsive to the Office action dated June 6, 2005. Claims 1-11 and 13-20 are pending in the application. Claims 1-11 and 13-20 are rejected. By way of the present amendment claims 1, 11, and 18 have been amended and new claims 21-25 have been added. In view of the amendments above, and the remarks below, Applicant respectfully requests reconsideration of the application under 37 C.F.R. § 1.111 and allowance of the pending claims.

## **Double Patenting Rejection**

The Examiner provisionally rejected claims 1-11 and 13-20 under the judicially created doctrine of double patenting over claims 1-7 and 9-25 of copending Application No. 10/085,564 from which the present application is a continuation-in-part. Submitted herewith is a Terminal Disclaimer stating that this application and copending Application No. 10/085,564 are commonly owned by Bioject Inc., which overcomes the provisional rejection of claims 1-11 and 13-20 under the judicially created doctrine of double patenting. As such, Applicant respectfully requests withdrawal of the provisional double patenting rejection.

# Rejections under 35 USC §§ 102 and 103

Claim 1 and its Dependent Claims

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Jacobsen et al. (U.S. Patent No. 5,833,632), March et al. (U.S. Patent No. 5,997,525), and Aldrich

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et al. (U.S. Patent No. 5,489,269); and under 35 U.S.C. § 102(e) as being anticipated by Paskar (U.S. Patent No. 6,623,449) and Goll (U.S. Patent No. 6,344,027). Claims 2-6 and 8-10, which all depend directly or indirectly from claim 1, stand variously rejected under 35 U.S.C. § 102(b) and/or (e) based on the above five references. Claim 7 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over any of the above five references. As explained below, Applicant disagrees with the rejections but has nonetheless made certain claim amendments to clarify what Applicant regards as his invention.

Amongst other structure, amended claim 1 recites a rigid end effector having a longitudinal axis configured into a shape wherein the end effector is <u>sufficiently rigid to maintain the shape of its longitudinal axis during use</u>. A "rigid" end effector is distinct from a "malleable and/or manipulatable" end effector, which may be adapted "to form around or within anatomical structures" during use, as discussed on page 12 of the specification. In particular, in a malleable and/or manipulatable end effector, the shape of the longitudinal axis may be manipulated during use such that the end effector may be steered or guided around or within anatomical structures during some laparoscopic, thoracoscopic, or arthroscopic procedures. In contrast to a malleable and/or manipulatable end effector, a <u>rigid</u> end effector, as recited in claim 1, is <u>sufficiently rigid to maintain the shape of its longitudinal axis during use</u>.

Referring first to the Jacobsen patent, Jacobsen does not disclose, teach, or suggest a device having a rigid end effector that is sufficiently rigid to maintain the shape of its longitudinal axis during use, as recited in amended claim 1. Instead, the only structure in Jacobsen that may be considered an end effector is the tubular guide wire 320 shown in Fig. 1. As provided in the abstract, the Jacobsen guide wire is designed to provide a catheter with "guidance to a target location in a vasculature passageway of a body." In particular, as described at col. 3, lines 4-5, Jacobsen discloses that "the shape of the guide wire can be controlled to a certain extent while disposed in vasculature or body cavities." Thus, rather than being rigid, the Jacobsen guide wire is malleable and/or manipulatable to allow ready navigation through the vasculature by altering or manipulating the shape of the longitudinal axis of the guide wire during use. Accordingly, Jacobsen does not disclose a rigid end effector that is sufficiently rigid to maintain the shape of its longitudinal axis during use, as described and claimed in the present application.

Referring now to the March patent, March does not disclose, teach, or suggest a device having a rigid end effector that is sufficiently rigid to maintain the shape of its longitudinal axis during use, as recited in amended claim 1. Instead, as shown in the various figures and described at col. 2, lines 62-63 and col. 4, lines 31-36, March discloses a <u>flexible</u> lasing transmission means that includes a <u>flexible</u> catheter 10. March's flexible catheter 10 is adapted to be introduced into "the patient's arterial system, generally through the femoral artery" such as to "facilitate introduction of the distal end

of catheter 10 into the patient's left ventricle." Thus, rather than being rigid, the flexible catheter of March is malleable and/or manipulatable to allow the distal end to be readily introduced into the patient's left ventricle along a route passing through the femoral artery, the iliac artery, and the aortic arch. Navigation of a flexible catheter through the femoral and iliac arteries and the aortic arch requires alteration or manipulation, during use, of the shape of the catheter's longitudinal axis. Accordingly, March does not disclose a rigid end effector that is sufficiently rigid to maintain the shape of its longitudinal axis during use, as described and claimed in the present application.

Regarding the Aldrich patent, Aldrich does not disclose, teach, or suggest a device having a rigid end effector that is sufficiently rigid to maintain the shape of its longitudinal axis during use, as recited in amended claim 1. In contrast, as shown in Figs. 1, 2, and 5 and described at col. 4, lines 2-28, the Aldrich patent discloses a <u>flexible</u> catheter 10 that includes "a flexible elongated member 11 and a lockable sleeve 26 positioned at the proximal end thereof, both formed from flexible plastic material tubes of different diameters." Thus, as described at col. 4, lines 5-6 and 65-66 and represented in Figs. 1 and 2, rather than being rigid, Aldrich's flexible elongated tube member is malleable and/or manipulatable to allow the distal portion of the flexible catheter to be manipulated into a "desired loop or pigtail configuration" by altering the shape of the longitudinal axis of the flexible catheter during use. Accordingly, Aldrich does not

disclose a rigid end effector that is sufficiently rigid to maintain the shape of its longitudinal axis during use, as described and claimed in the present application.

Referring now to the Paskar patent, Paskar does not disclose, teach, or suggest a device having a rigid end effector that is sufficiently rigid to maintain the shape of its longitudinal axis during use, as recited in amended claim 1. Instead, as shown in various figures and described throughout the specification, Paskar discloses a reformable catheter having a longitudinal axis that is easily reshaped during use. For example, as described at col. 2, lines 36-41, Paskar discloses a transformable catheter that "can be easily and simply reshaped into a variety of different shapes as desired by the user" and can "be reformed in the body to other desired shapes." Further, as described at col. 13, lines 32-37. Paskar's catheter is a "curvable surgical element" having a "curvable or deflectable Thus, rather than being rigid, the transformable catheter of Paskar is distal tip." malleable and/or manipulatable to allow the catheter to be "reformed in the body to other desired shapes" by altering or manipulating the shape of the catheter's longitudinal axis during use. Accordingly, Paskar does not disclose a rigid end effector that is sufficiently rigid to maintain the shape of its longitudinal axis during use, as described and claimed in the present application.

Referring now to the Goll patent, Goll does not disclose, teach, or suggest a device having a rigid end effector that is sufficiently rigid to maintain the shape of its longitudinal axis during use, as recited in amended claim 1. Instead, as described at col.

4, lines 14-25, Goll discloses a device having an elongate shaft 14 with a flexibility "suitable for navigation from a remote access site to the treatment site within the human body." In particular, the elongate shaft of Goll is sufficiently flexible for "intravascular navigation to the coronary tissue from a remote access site in the femoral artery," which requires transiting the aortic arch, or for "transthoracic navigation to the coronary tissue from a remote access point in the upper thorax." Thus, rather than being rigid, the elongate shaft of Goll is malleable and/or manipulatable to permit intravascular or transthoracic navigation of the elongate shaft to the coronary tissue from a remote access site. Either type of navigation requires alteration or manipulation of the shape of the longitudinal axis of the elongate shaft during use. Accordingly, Goll does not disclose a rigid end effector that is sufficiently rigid to maintain the shape of its longitudinal axis during use, as described and claimed in the present application.

For at least the reasons discussed above, the cited references do not disclose, teach or suggest a device as claimed in amended claim 1. Claims 2-10 contain further limitations that distinguish the cited references. Accordingly, amended claim 1 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 1-10 under 35 U.S.C. §§ 102 and 103 be withdrawn.

Applicant has added new claims 21-23, which depend from claim 1. Support for the new claims can be found throughout the specification as filed and no new matter is added. Applicant believes that claim 1 is now allowable. Therefore, new claims 21-23 are similarly allowable.

Claims 11 and 18 and their Respective Dependent Claims

Claims 11 and 18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Jacobsen et al. (U.S. Patent No. 5,833,632), March et al. (U.S. Patent No. 5,997,525), and Aldrich et al. (U.S. Patent No. 5,489,269); and under 35 U.S.C. § 102(e) as being anticipated by Paskar (U.S. Patent No. 6,623,449) and Goll (U.S. Patent No. 6,344,027). Claims 12-17, which all depend directly or indirectly from claim 11, and claims 19 and 20, which depend directly or indirectly from claim 18, stand variously rejected under 35 U.S.C. § 102(b) and/or (e) based on the above five references. Applicant disagrees with the rejections but has nonetheless made certain claim amendments to clarify what Applicant regards as the invention. For at least reasons similar to those stated above, Applicant respectfully submits that claims 11 and 13-20 patentably distinguish the cited references, and requests withdrawal of the rejections of those claims.

Applicant has added new claims 24 and 25, which depend from claim 11. Support for the new claims can be found throughout the specification as filed and no new matter is added. Applicant believes that claim 11 is now allowable. Therefore, new claims 24 and 25 are similarly allowable.

### Conclusion

Applicant believes that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, Applicant respectfully requests that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

## **CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on August 19, 2005.

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